REMARKS

Claim 1 has been amended so that it recites that the polar lipid is a glycolipid and the water and alcohol are present. A new claim 41 is presented based on page 2, line 9.

In the last Office Action before the RCE, claims 1, 31, 32 and 34-39 were rejected under 35 U.S.C. 102 and claims 33 and 40 under 34 U.S.C. 103 over Herslof. Those rejections should not be repeated.

The tablet claimed in the present application comprises a solid oral heparin composition disposed in the form of a tablet in which the solid oral heparin composition has a melting point of at least 25 degrees C and consists essentially of a continuous lipid component comprising a polar and non-polar lipid, with water and an alcohol, and heparin. The Herslof reference does not teach or suggest a solid oral heparin composition in any form.

Herslof relates to spherical lipid bilayers formed in vivo (biosomes) and a matrix thereof (biosome forming matrix or BFM). The BFM is not a solid but instead is a liquid or semi-solid at room temperature as indicated at column 4, lines 27-28. Room temperature is 22°C, albeit usually expanded to 21-23°C, as established by the attached on-line dictionary printout, (not "about 21-25°C" as asserted in the last Office Action), while the instant claims call for the composition having a melting point of at least 25°C (not "about 25°C" as asserted in the last Office Action), which means that the claimed composition does not melt at the "room temperature" where the BMF is not solid. The fact that the composition is a liquid or semi-solid is also acknowledged in the first line of claim 1. The reference does disclose BFMs containing a low molecular weight

heparin sold under the trademark Fragmin but this is a liquid which would either reinforce the liquid nature of the BFM if the BFM was liquid or make the BFM even less solid when it was a semi-solid in the first instance. Since Herslof fails to teach a solid composition having a melting point of at least 25 degrees C, a novelty rejection based on 35 U.S.C. 102 is clearly untenable. Since Herslof does not teach or suggest how a solid material should be made and does not suggest using a non-solid to make a tablet, a rejection based on Section 103 is also inappropriate.

Also in the last Office Action prior to the RCE, claims 1, 5-19, 22, 24-27 and 29-40 were rejected under 35 U.S.C. 103 over Nyqvist in view of Rosenberg (using the corresponding U.S. published application as an English language equivalent). This rejection should also not be repeated.

The disclosure of Nyqvist is essentially the same as that of Herslof. This is not surprising since the Nyqvist invention is based on the lipid system described in a Swedish patent application (column 1, lines 23-24) which is the priority application on which Herslof is based. Some of the examples in the two patents even appear to be the same (compare Nyqvist example 7 with Herslof example 15). It appears that the essential difference between these two references is that one does not contain water and the other does. Accordingly, Nyqvist suffers from the same deficiencies as Herslof in that it discloses a liquid or semi-solid composition rather then a solid composition and tablet containing the solid composition.

The deficiencies in Nyqvist are not remedied by reliance on Rosenberg. This additional reference relates to formulations based on the combination of, inter alia, heparin with a formulation base which contains both a lipid component and a polymer

component. It is clear from the disclosure of this reference that absent the polymer, the composition is not a solid. In this connection, the attention of the Examiner is respectfully invited to paragraph [0052] which states:

> "the polymer component of the formulations of the invention can also be understood as a polymeric binder which at least partially forms a polymer matrix. Binders for the purpose of the invention are solid, meltable solvents. The polymer matrix serves especially to take up, and in particular dissolve, at least a part of the liquid component and this preferably leads to the formation of molecular dispersions."

A molecular dispersion is where a component is "homogeneously dispersed in a solvent". See paragraph [0043]. The examples in Rosenberg further show that not only is the polymer component a material which has a material effect on the characteristics of the composition, but also the amount of the polymer has a material effect. Thus, examples 1 and 2 in Rosenberg disclose preparing solid products from which tablets can be made and in which the polymer constitutes either 64 or 70% of the composition. In contrast, the composition of example 5 which contained 3% of the polymer was a liquid composition which could be packed into hard gelatin capsules while still warm. To try to avoid the essential nature of the polymer by saying the reference does not "directly teach that a polymer is necessary" ignores all of the foregoing and is not valid. As will be appreciated by the Examiner, the "consisting essentially of" language in the instant claims serves to exclude the presence of the polymer which affects the basic characteristics of a lipid-heparin combination by sorbing the combination to realize a solid composition.

With regard to the assertion made at the bottom of page 7 of the aforementioned last Office Action, it should be appreciated that the melting point of the relevant compositions is not exclusively determined by the non-polar lipid but rather by the interplay of non-polar lipid, phosphatidyl choline, water, and possibly other components. Also, it should be noted that the phosphatidyl choline, when contacted with an excess of water, results in the formation of bi-layered structures but there is no foundation for assigning a solid state to any particles formed because that would be the same as assigning a solid state to the entire bi-layered structure.

In light of all of the foregoing considerations, it is respectfully submitted that the prior art does not teach or suggest a solid oral heparin composition nor a tablet containing the solid oral heparin composition nor a method of using the tablet nor a method of making the tablet. Accordingly, withdrawal of all of the rejections under 35 U.S.C. 102 and 103 is respectfully requested.

Respectfully submitted,

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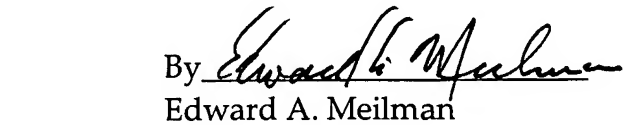
By 

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Nätet

Relaterade fraser: room temperature offset room temperature and pressure room temperature superconductor room temperature vulcanizing bring to room temperature

Definition av **Room Temperature** på nätet på engelska:

- This is an often quoted figure of around 20°C.
  www.air-conditioning-directory.co.uk/glossary.htm

- used colloquially to mean the ordinary temperature one is accustomed to find in dwellings. Technically it can mean the temperature of (l) a room in which a refrigerator is being operated or tested; (2) a room being conditioned for the occupant's comfort
  www.learn.londonmet.ac.uk/packages/clear/glossary/glosmtor.html

- It's the temperature at which red wine is served. A hundred years ago homes were much cooler and room temperature was 16 -17°C, which is ideal for wine.
  www.mynrma.com.au/afw_winespeak.asp

- the normal temperature of room in which people live
  wordnet.princeton.edu/perl/webwn

- Room temperature, in laboratory reports, is taken to be roughly 21–23 degrees Celsius (70–73 degrees Fahrenheit), or 294–296 kelvins. The "standard" room temperature is 22 °C (72 °F or 295 K).
  en.wikipedia.org/wiki/Room_temperature